UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS AMERICA, INC., and TAKEDA IRELAND LIMITED,

Plaintiffs,

v.

TORRENT PHARMACEUTICALS LTD. and TORRENT PHARMA INC.,

Defendants.

TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS AMERICA, INC., and TAKEDA IRELAND LIMITED,

Plaintiffs,

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INDOCO REMEDIES LTD.,

Defendant.

Civil Action No. 17-3186 (SRC)(CLW) (CONSOLIDATED)

(Filed Electronically)

Civil Action No. 17-7301 (SRC)(CLW)

[PROPOSED] FINAL JUDGMENT

NOW THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

- 1. This Court has jurisdiction over the Parties and subject matter of this action.
- 2. Final Judgment is entered in favor of Takeda and against Torrent on all claims and counterclaims with respect to the '689 patent. Torrent's ANDA Products that are the subject of ANDA Nos. 21-0159, 21-0160, and 21-0161 infringe claims 4 and 12 of the '689 patent. Claims 4 and 12 of the '689 patent are not invalid.
- 3. Final Judgment is entered in favor of Takeda and against Indoco on all claims and counterclaims with respect to the '689 patent. Indoco's ANDA Products that are the subject of ANDA Nos. 209998 and 210002 infringe claims 4 and 12 of the '689 patent. Claims 4 and 12 of the '689 patent are not invalid.
- 4. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Torrent's ANDA Nos. 21-0159, 21-0160, and 21-0161 shall be no earlier than June 27, 2028, the expiration of the '689 patent, including any extensions by FDA.
- 5. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Indoco's ANDA Nos. 209998 and 210002 shall be no earlier than June 27, 2028, the expiration of the '689 patent, including any extensions by FDA.
- 6. Pursuant to 35 U.S.C. § 271(e)(4)(B), Torrent and its officers, agents, servants, employees, and attorneys, and other persons in active concert or participation with any of them, are hereby enjoined from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States the products that are the subject of ANDA Nos. 21-0159, 21-0160, and 21-0161 until June 27, 2028, the expiration of the '689 patent, including any extensions by FDA.

- 7. Pursuant to 35 U.S.C. § 271(e)(4)(B), Indoco and its officers, agents, servants, employees, and attorneys, and other persons in active concert or participation with any of them, are hereby enjoined from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States the products that are the subject of ANDA Nos. 209998 and 210002 until June 27, 2028, the expiration of the '689 patent, including any extensions by FDA.
- 8. On or before February 17, 2020, Torrent shall inform FDA of this Final Judgment and that, for ANDA Nos. 21-0159, 21-0160, and 21-0161, a final judgment has been entered that all of the asserted claims of the '689 patent are infringed and not invalid. Torrent shall provide confirmation of such communication to Takeda within seven days thereof.
- 9. On or before February 17, 2020, Indoco shall inform FDA of this Final Judgment and that, for ANDA Nos. 209998 and 210002, a final judgment has been entered that all of the asserted claims of the '689 patent are infringed and not invalid. Indoco shall provide confirmation of such communication to Takeda within seven days thereof.
- 10. As the prevailing party, Takeda is awarded its costs, in an amount to be determined by the Clerk of Court.
- 11. If any party appeals from this Final Judgment, any Bill of Costs by Takeda shall be filed and served within thirty days after issuance of the mandate from any such appeal (which filing shall be considered timely); otherwise, if neither party appeals, any Bill of Costs by Takeda shall be considered timely if filed and served within thirty days after the time to file a notice of appeal has expired.
- 12. All pending motions and other outstanding requests for relief not specifically addressed herein are DENIED.

IT IS SO ORDERED this ______ day of _____

STANLEY R. CHESLER United States District Court Judge